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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/378,759	08/23/1999	GARY M. FOX	06843.0027-0	9481

7590 09/09/2003

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/378,759	FOX ET AL.	
	Examin r	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE f this communication app ars on th c ver sheet with the corresp ndenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *28,29,31 and 36-56* is/are pending in the application.

4a) Of the above claim(s) *28,29,31,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *42-56* is/are rejected.

7)☐ Claim(s) *38-41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *19 February 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/19/03 has been entered. Applicant is further notified that the amendments and arguments presented 2/19/03 have been entered in full and are considered below.

New issues:

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment of 2/19/03 to claim 47 introduces new matter into the specification. Claim 47 has been amended to include the limitation that the antibody be raised against at least a portion of a polypeptide comprising SEQ ID NO: 11, wherein the portion is not identical to any portion of CeK5. Upon reading the specification, the skilled artisan would not recognize that Applicant was in possession of such a genus of claimed antibodies. There is no statement in the specification that antibodies should be raised in this way, and nor does there appear to be any motivation or suggestion that this should be done.

Claim 47 is also objected to as introducing new matter into the specification. As set forth above, there does not appear to be any support for the proposed limitation. Applicant argues at page 2 of Paper 20, that support for the amendment can be found at, e.g., page 4 lines 20-21.

Applicant asserts that the specification presents a positive recitation of Cek5, and thus, the negative recitation of Cek5 in the claims is supported, MPEP 2173.05(i). This argument has been fully considered but not deemed persuasive. The specification merely indicates that Cek5 is the chicken homolog of Hek5. The skilled artisan would not interpret this statement as being a positive counterpart to the claimed antibody, e.g. the specification does not teach that antibodies should be raised to at least a portion of a polypeptide comprising SEQ ID NO: 11, wherein the portion is identical to any portion of CeK5 - such a positive recitation might be viewed as Applicant suggests, however there appears to be no such positive statement.

Claims 38-41 are objected to because claim 38 encompasses several non-elected patentably distinct inventions (Paper 5, 12/19/03); Applicant is required to delete the non-elected inventions of 38(b) and 38(c).

Outstanding Issues:

Applicant is notified that the Drawings submitted 2/19/03 are accepted.

Claims 43, 46, 51 and 56 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims require a pharmaceutical composition yet the specification does provide sufficient guidance as to what the antibody is therapeutically effective for; and neither can such a use be reasonably inferred from the prior art, as set forth previously.

Applicant argues that the recitation of "pharmaceutical composition" is in the preamble and therefor carries no patentable weight, MPEP 2111.02. This argument has been fully considered but not deemed persuasive. The claim requires a pharmaceutical composition comprising the antibody. The intended use is as a pharmaceutical composition. As set forth previously, the term "pharmaceutical composition" implicitly requires that the composition can be used in a therapy or treatment. The fact that it may be used for something else, as Applicant suggests, is beside the point.

The rejection of claim 47 rejected under 35 U.S.C. 102(b) as being anticipated by Pasquale EB, Cell Regulation 2(7)523-534, 1991, as set forth in item 10 of Paper 15, 4/4/02, of Paper 12 is withdrawn in view of Applicant's amendments.

However, claim 52 stands rejected under 35 U.S.C. 102(b) as being anticipated by Pasquale EB, Cell Regulation 2(7)523-534, 1991, as set forth in item 10 of Paper 15, 4/4/02, of Paper 12. It is noted that the previous office action had indicated that the rejection of claim 52 would be withdrawn (see item 4 of Paper 21). The examiner erroneously assumed that claim 52 depended from claim 47.

Applicant argues that the Pasquale antibodies were not raised against "at least a portion of human Hek5 (SEQ ID NO: 11)" and thus cannot anticipate the claim. This argument has been fully considered but not deemed persuasive. As set forth previously, because the two proteins are 95% identical, they contain many more of the same "portions" than those portions that differ between them.

The rejection of claims 38-41, 48-50, under 35 U.S.C. 103(a) as being unpatentable over Pasquale EB, Cell Regulation 2(7)523-534, 1991, as has been applied to claim 47, in view of U.S. Patent No: 4816567, is withdrawn in view of Applicant's amendments.

However, as discussed above, claim 52 remains rejected as being anticipated by Pasquale and thus dependent claims 53-54 and claims 42, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pasquale EB, Cell Regulation 2(7)523-534, 1991, as has been applied above to claim 52, in view of U.S. Patent No: 4816567. Additionally it is noted that claims 42, 44, and 45 were erroneously indicated as being withdrawn from the rejection in the previous office action. Claims 42, 44, and 45 simply require that the monoclonal antibody bind to a sequence as set forth in SEQ ID NO: 11. As set forth previously, many of the antibodies raised against chicken Cek5 would be expected to bind SEQ ID NO: 11 because the two proteins share many more portions of amino acid sequence in common then they do that differ.

As set forth previously, 4816567 teaches that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while

CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success, to make a monoclonal, chimeric, or CDR grafted antibodies according to U.S. Patent No: 4816567 when practicing the invention of Pasquale EB. The motivation to do so is provided by U.S. Patent No: 4816567 wherein in is indicated that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7). Applicant's arguments regarding Pasquale, as they relate to claim 42, 44, 45, and 52, have been discussed above, i.e. that because the two proteins are 95% identical, they contain many more of the same "portions" than those portions that differ between them, and thus most of the antibodies produced against portions of one would be expected to be identical to most of the antibodies raised against the other.

Claims 42, 44, 45, 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwase et al., Biochem. Biophys. Res. Comm. 194(2)698-705, 1993 in view of U.S. Patent No: 4816567, as set forth in item 10 of Paper 19.

Applicant argues that Iwase et al. never assert that the H1 polypeptide is upregulated and that the mRNA encoding H1 was all that was asserted to be upregulated. Applicant is technically correct, however, one of ordinary skill in the art would read Iwase et al. with the presumption that the polypeptide was also, more likely than not, up regulated as well, and that the primary focus of Iwase et al. is the potential role of the encoded protein and not the mRNA,

e.g. in the Introduction (pg 698) Iwase et al. discuss the role of protein kinases in gastric cancers - thus referring to the protein and not to mRNA. The first sentence of the summary indicates that the focus of this plan of research is to find protein tyrosine kinases, identification of mRNAs encoding the kinases being a first step in this process. Regardless, it is readily apparent that one of ordinary skill in the art would be motivated to make antibodies to the protein sequence disclosed by Iwase et al. to study the role of H1 in the development of gastric cancers, e.g. in the potential for diagnosis and/or treatment, as set forth previously.

Conclusion

No claims are allowable

Please note the new official fax number below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

September 7, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600